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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/550,173	04/14/2000	Norihisa Ooe	2185-0424-SP	8838

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EXAMINER

LAMBERTSON, DAVID A

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 12/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/550,173

Applicant(s)

OOE ET AL.

Examiner

David A. Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed October 20, 2004.

Amendments were made to the claims.

Claims 1-9 and 11-17 are pending and under consideration in the instant application.

Any rejection of record in the previous Office Action, mailed April 20, 2004, that is not addressed in this action has been withdrawn.

Because this Office Action only maintains rejections set forth in the previous Office Action and/or sets forth new rejections that are necessitated by amendment, this Office Action is made FINAL.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

It is noted that the instant claims have been amended to contain the term "stably transformed with" in place of the term "securely maintaining." Because the term "stably transformed with" is a relative term, the term is given a broad interpretation for the application of art, where a cell maintaining a nucleic acid construct for any length of time over two days is considered to meet the limitation of "stably transformed with," absent evidence to the contrary (such as an explicit definition in the instant specification indicating what length of time is necessary to meet said limitation). Because the previously recited art meets this limitation (e.g.,

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stably transformed for 20 generations, which is ~ 20 days in mammalian cells), the art is applied as set forth previously.

Claims 1, 3-9, 11 and 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bradfield '283 (as cited previously) in view of Waldman (as cited previously). **This rejection is maintained for the reasons set forth in the previous Office Action.**

Claims 1, 3-9, 11, 13-17, 2* and 12* are rejected under 35 U.S.C. 103(a) as being unpatentable over Bradfield '283 in view of Waldman as applied to claims 1, 3-9, 11 and 13-17 above, and further in view of Kushner '638 (as cited previously). (Note-* represents the claims that are rejected in view of the newly cited reference). **This rejection is maintained for the reasons set forth in the previous Office Action.**

Response to Arguments Concerning Claim Rejections - 35 USC § 103

Applicant's arguments filed October 20, 2004 have been fully considered but they are not persuasive. The following grounds of traversal have been presented:

1. Applicant contends that the fact that the instant claims do not contain limitations set forth in Example 4 of the instant specification is not a moot point with respect to the traversal of the rejections (see for example page 14 of Applicant's response). This is because "the transformed cells of the present invention are not limited to the specific constructs shown in Example 4" and "the cells of the present invention may be prepared by using a 'minimum promoter'" ... wherein

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“the constructs disclosed in Example 4...merely represent non-limiting examples of use of a minimum promoter” (see for example page 15, first paragraph of Applicant’s response).

2. Applicant contends that none of the references teach the instant invention, specifically “an animal cell stably transformed with a DNA comprising in a molecule, a reporter gene (a) connected downstream from a transcription control region which substantially consists of a recognition sequence of the ligand-responsive transcription control factor and a minimum promoter, and selective marker gene (b), would show higher sensitivity in detection of ligand-responsive transcription activity” (original emphasis; see for example page 15, second paragraph of Applicant’s response).

3. Applicant argues that the motivation to combine Bradfield ‘283, Waldman and Kushner ‘683 is so general that it would not lead the skilled artisan to “chose [sic] the specific promoter (i.e., minimum promoter) utilized in the present invention” (see for example page 16, top paragraph of Applicant’s response).

Applicant’s arguments have been fully considered, but are not convincing for the following reasons:

1. Applicant and the Office clearly agree that the claims are much broader in scope than what is set forth in Example 4 of the instant specification. That being said, the fact that the prior art does not teach the constructs of Example 4 of the instant specification cannot be the basis for the successful traversal of the instant rejections. In other words, the prior art does not need to teach the specific constructs of Example 4 in order to anticipate/make obvious the claimed invention.

It was in this sense that Applicant’s prior traversal was deemed moot.

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As set forth previously (and which will be briefly reiterated below in section 2), the applied references meet each and every limitation of the claimed invention, and thus make the invention obvious. Applicant has made no indication as to what elements of the claim are not set forth in the applied references, and thus has not provided a reason to withdraw the claimed rejection.

2. It is reiterated that the applied references teach each and every element of the claimed invention. Specifically, the previous Office Action reiterated on pages 5-6:

Bradfield describes the use of mammalian cells expressing the Ah receptor and the ARNT receptor in assays to detect agonists of the transcriptional activities of the receptor (see column 23, lines 30-33 and lines 41-46) by measuring the activity of a reporter gene that has been operatively linked to a transcriptional response element for the Ah receptor (see column 2, lines 56-62). The Ah receptor is maintained in the cell on a plasmid also containing a selectable marker, while the reporter gene is present on a second plasmid, but in the same molecule with a second selectable marker (see Figure 11). Furthermore, Bradfield explicitly indicates that the Ah receptor and ARNT *or* the chimeric Ah receptor can be expressed in mammalian cells (see column 23, lines 44-46). This must be interpreted to mean the full-length Ah receptor was used in the assay described by Bradfield. Waldman then teaches a method of securing DNA within a cell for up to 20 generations of growth. Motivation to combine these teachings is provided by Waldman which indicates their method is fast, economical and of general utility" (see abstract, last sentence). These references can be further combined with Kushner, who teaches a method for screening compounds in cells (including mammalian) that both activate (agonist) and block (antagonist) the stimulation of transcription of genes, some of which are regulated by hormone receptors, using a minimal promoter region comprised of a TATA box (see especially column 14, lines 39-49 and 57-64 and column 15, lines 32-41 and 60-63). Motivation to combine these teachings comes from the desire to identify compounds that could attenuate (antagonize) the affects of hormone receptor transcription response hyperactivation, which is prevalent with respect to the estrogen receptor and its role in breast cancer formation (see Kushner column 15, line 40-41).

These teachings, by encompassing all of the limitations set forth in the claims, make the instant claims obvious despite Applicant's generalized remarks. Applicant has not indicated what limitation of the instant claims is not taught by Bradfield, Waldman and Kushner; Applicant simply states that they do not teach the claimed invention. However, all of the

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structural and functional elements and method steps of the instant claims are taught by the

recited references. As such, the rejection is maintained in view of Applicant's arguments.

3. First, it is noted that there is nothing to prevent the use of a general motivation statement in formulating an obviousness-type rejection. This is especially true in instances where the claims that are being rejected as obvious are themselves very general. In the instant case, the teachings of Kushner are broadly applicable to minimum promoters, just as the instant claims are broadly drawn to the use of minimum promoters. In other words, Applicant is not claiming the use of a "specific promoter" as alleged; rather they are claiming the use of *any* minimum promoter. This is not a "specific promoter" (i.e., for a specific gene or gene cluster), thus Applicant's claims are general in terms of the use of a minimum promoter. That being said, it is unclear why a general motivation statement, indicating the use of any minimum promoter (as also set forth in the instant claims) would not be applicable as a proper motivation statement.

Furthermore, Kushner teaches their methods are useful in identifying compounds to antagonize the effects of hormone receptors, of which the Ah receptor taught by Bradfield is a member. Thus, the skilled artisan would understand the teachings of Kushner were applicable to the specific promoter as taught by Bradfield, and would recognize that this is not merely a generalized motivation, as alleged. Because the teachings of Kushner are equivalent in scope to the limitations of the instant claims, and are directly related to the specific promoter used by Bradfield, Applicant's argument that the motivation statement is "too broad" is not found persuasive and the rejection is maintained.

In conclusion, Applicant has not demonstrated which limitation of the instant claims is not taught by the combined teachings of Bradfield, Waldman and Kushner. The combined

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references teach each and every limitation set forth in the claims, both in terms of structure-function elements and method steps. Furthermore, an adequate motivation statement was given to combine the teachings, despite Applicant's argument that it is too generalized. Thus, the rejections are maintained in view of Applicant's traversal.

Allowable Subject Matter

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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AU 1636



JAMES KETTER
PRIMARY EXAMINER